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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JANSSEN PRODUCTS, L.P., and
JANSSEN SCIENCES IRELAND
UNLIMITED COMPANY,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA)
INC., AND CADILA HEALTHCARE
LTD.,

Defendants.

Civil Action No. 3:20-cv-00787
(FLW)(TJB)

(Filed Electronically)

CONSENT JUDGMENT AND ORDER

WHEREAS, this action for patent infringement (“the Litigation”) was brought by Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company (collectively, “Janssen”) against Defendants Zydus Pharmaceuticals (USA) Inc. (“Zydus USA”) and Cadila Healthcare Limited (“Cadila”) (collectively, “Zydus” and, together

with Janssen, the “Parties”) for infringement of United States Patent Nos. 7,700,645 (the “’645 Patent”); 8,518,987 (the “’987 Patent”); 7,126,015 (the “’015 Patent”); and 7,595,408 (the “’408 Patent”) (collectively, the “Janssen Patents”);

WHEREAS, Janssen currently markets in the United States, pursuant to New Drug Application No. 21-976, tablets containing darunavir ethanolate for the treatment of HIV-1 infection, all strengths of which Janssen currently sells under the trade name PREZISTA® (the “Prezista Product”);

WHEREAS, Janssen’s commencement of the Litigation was based on its receipt of notice from Zydus USA that it had filed with the United States Food and Drug Administration (“FDA”) Abbreviated New Drug Application (“ANDA”) No. 214085 (the “Zydus ANDA”) containing a “paragraph IV certification” with respect to the ’645 and ’987 Patents, and seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States of generic versions of darunavir ethanolate tablets (the “Zydus Product”), prior to the expiration of the ’987 and ’645 Patents;

WHEREAS, Zydus USA is a wholly-owned subsidiary of Cadila;

WHEREAS Zydus agrees that the asserted claims of the Janssen Patents are valid and enforceable solely with respect to the manufacture, use, offer for sale, sale, and importation of the Zydus Product in the United States;

WHEREAS, Zydus agrees that the Zydus ANDA submission and the commercial manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States of the Zydus Product before the expiration of each of the Janssen Patents would constitute acts of infringement of the Janssen Patents;

WHEREAS, the Parties desire to avoid substantial litigation costs that would otherwise be incurred and conserve the Court’s resources by resolving the Litigation, including appeals therefrom;

WHEREAS, Zydus and Janssen have agreed to resolve this litigation, including the right of appeal, for good and valuable consideration recognized by the Parties;

WHEREAS, the Parties have agreed to terminate the pending litigation by the entry of this Judgment and Order; and

WHEREAS, the Parties now consent to this Judgment and Order.

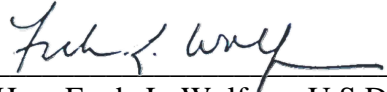
The Court, upon the consent and request of the Parties, and upon due consideration and for good cause shown, issues the following Consent Judgment and Dismissal Order.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

1. Subject matter jurisdiction, personal jurisdiction, and venue are all proper in this Court.
2. The submission of the Zydus ANDA to the FDA and the commercial manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States of the Zydus Product before the expiration of each of the Janssen Patents would constitute acts of infringement of the Janssen Patents, absent authorization from Janssen.
3. The asserted claims of the Janssen Patents are valid and enforceable solely with respect to the manufacture, use, offer for sale, sale, and importation of the Zydus Product in the United States.
4. Zydus USA, Cadila and their Affiliates are hereby enjoined from manufacturing, using, offering for sale, selling in the United States, or importing into the United States, the Zydus Product until the expiration of each of the Janssen Patents, including any patent term extensions and/or patent term adjustments and during the period of any associated exclusivity, other than pursuant to authorization from Janssen or as otherwise recognized by the Parties.

5. All affirmative defenses, claims and counterclaims in this action are hereby dismissed without prejudice.
6. Each party shall bear its own fees and costs in connection with this action, including attorneys' fees.
7. The Parties waive all right to appeal or otherwise move for relief from this Judgment and Order.
8. This Court shall retain jurisdiction of this action and over the Parties for purposes of enforcement of the provisions of this Judgment and Order.

IT IS SO ORDERED, this 19th day of June, 2020


Hon. Freda L. Wolfson, U.S.D.J.

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